NIH POLICY MANUAL

54444 – Evaluation of Grant Progress Reports by Program Officials Issuing Office: OEP/OER/OD 435-2769 Release Date: 10/01/01

1. **Explanation of Material Transmitted**: This chapter contains the policy and procedures for monitoring scientific project performance on National Institutes of Health grant awards.

2. **Filing Instructions**: Remove: None

Insert: NIH Manual Chapter 4444 dated 10/01/01

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- **A. Purpose:** This chapter states NIH policies and procedures for monitoring extramural research progress by Program Officials/Project Officers. This evaluation complements the fiscal and administrative evaluation by Grants Management Specialists and provides a format for the evaluation of progress on noncompeting NIH grants and cooperative agreements. The standard established in this policy does not preclude awarding units from developing additional or customized reporting information for specific programs or mechanisms provided all elements of the standard format are included in the process.
- **B.** Applicability: This policy is applicable to all NIH non-competing progress reports. Exception: invention reporting is not required for educational awards (i.e., training grants, fellowships).
- **C. Background**: Grant project performance reports are required no less than annually by regulation (45 CFR 74.51, link provided below) and are necessary for Program Official/Project Officer evaluation of scientific progress. Program Officials/Project Officers review these reports to evaluate, monitor and assess scientific progress to ensure that funds are appropriately expended and that the commitment of additional funds is supported by the reasonable expectation of continued progress on the project.
- **D. Policy**: Grant project performance monitoring is required on an annual basis. Evaluation of progress must be made and forwarded to grants management in sufficient time to allow a continuation award to be issued prior to the committed budget period start date. Scientific progress of the grant must be determined to be satisfactory by a Program Official/Project Officer before additional funds can be awarded for continuation of the project. Itemized below are areas that must be addressed by Program Officials/Project Officers in reviewing annual progress reports. Awarding units may establish additional requirements. Appendix 1 also provides this information and source documentation.
 - o Is progress satisfactory?
 - o Is there a change in the scope, goals, or objectives of the project?
 - o Is there is a change in key personnel?
 - o Is there evidence of scientific overlap?
 - o Determine if there are human subject issues or concerns.
 - o Determine if there are animal welfare issues or concerns.
 - o Determine if an invention is being reported in the progress report.
 - o Other issues that must be resolved before issuing an award.

E. Responsibilities:

Grants Management Officers are responsible for assuring that all grant awards: conform to statutory authority, regulations, policy directives, and administrative guidelines; are within available funds; constitute valid obligations for recording in the official accounting records; include appropriate terms and conditions of award; and, are issued prior to the committed budget period start date.

Program Officials/ Project Officers are responsible for evaluating the scientific/technical progress on all non-competing grant progress reports on an annual basis, and keeping the Grants Management

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Officer/Grants Management Specialist informed of concerns/changes that may impact on future funding, require close project monitoring, or special terms of award. If progress is satisfactory and reporting conditions have been met, the completed monitoring report should be signed and forwarded to the Grants Management Officer/Grants Management Specialist in sufficient time to allow a continuation award to be issued prior to the committed budget period start date.

F. References:

- 45 CFR 74.51(d) Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments, and Indian Tribal Governments --Monitoring and Reporting Program Performance http://www4.law.cornell.edu/cfr/45p74.htm#45p74s51
- 45 CFR 92.40(b)(2) Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments -- Monitoring and reporting program performance. http://www4.law.cornell.edu/cfr/45p92.htm#45p92s40
- 3. NIH Grants Administration Manual Part 4.1.04.604 Responsibilities of NIH Grants Administration Staff. http://odoerdb2.od.nih.gov/gmac/sources/nihgam_4_104_604.html
- 4. DHHS Grants Policy Directive Part 1.04 General HHS Responsibilities http://www.hhs.gov/grantsnet/adminis/gpd/gpd104.htm
- 5. DHHS Grants Policy Directive Part 3.06 Post Award Reports and Records http://www.hhs.gov/grantsnet/adminis/gpd/gpd306.htm
- 6. PHS Application Kits http://grants.nih.gov/Grants/OER.htm
- 7. NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps 2001/part iia 7.htm
- **G. Procedures:** The Grant Project Performance Monitoring Report (see Appendix 1) must be completed by the Program Official/Project Officer prior to additional funds being awarded for continuation of the project. The report should be forwarded to the Grants Management Specialist and made part of the official grant file. The name of the Program Official/Project Officer evaluating the progress report and the date of the review must be included as part of the record.

These reports may be prepared and processed electronically. The ICO module of the IMPAC II system will be modified to reflect this policy.

H. Records Retention and Disposal: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Section 4000 covers NIH grants and awards and Section 1100-G covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or

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have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls:

- 1. Office Responsible for Reviewing Management Controls Relative to this Chapter: Responsibility for monitoring compliance with this chapter resides with the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER). Compliance issues will be referred to the Director, Office of Extramural Programs (DOEP).
- 2. Frequency of Review: On-going review, no less than every five years.
- 3. Method of Review: OPERA will use the NIH Grants Management Compliance Model (GMCM) to maintain appropriate oversight of the use of grant progress reports. The GMCM contains a file review component to ensure that I/C grant files are properly maintained and processed with regard to monitoring progress performance. The GMCM will monitor these reports. Until this monitoring can be accomplished electronically using the ICO module of IMPAC II system, the official grant file will be documented with a copy of the report signed and dated by the Program Official/Project Officer. An award will not be released until the report has been completed and issues satisfactorily addressed.

Reports of findings and recommendations resulting from GMCM reviews or other similar types of reviews will be issued to assess compliance with the policy stated in this chapter. Common issues will be brought to the Project Officers/Program Officials Forum (POPOF) for resolution and corrective action. In addition, the DOEP will be routinely apprized of any difficulties in the implementation of this policy. Depending upon the nature and the extent of problems found, if any, the Grants Management Compliance Board or the DOEP may recommend additional review, policy guidance and/or training of staff.

Review Reports are sent to: DDER and DOEP.

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Grant Project Performance Monitoring Report

Grant Number: Principal Investigator: Program Official/Project Officer:		Date:		
1. Is progress satisfactory?	ſ] yes	Γ] no
If no, provide a brief explanation and recommendation.		1,7 ***		
http://grants.nih.gov/grants/policy/nihgps 2001/part iia 7.htm				
2. Is there a change in the scope, goals, or objectives of the project?	[] yes	[] no
If yes, does this change benefit the project and is it approved?	[] yes	[] no
If there is no benefit, please provide a brief explanation.				
http://grants.nih.gov/grants/policy/nihgps 2001/part iia 5.htm				
3. Is there a change in key personnel or their level of effort?	[] yes	[] no
If yes, describe the change and the impact.				
http://grants.nih.gov/grants/policy/nihgps 2001/part i 1.htm				
4. Is there evidence of scientific overlap?	[] yes	[] no
If yes, please note details and recommendation.				
http://www3.od.nih.gov/oma/manualchapters/grants/4519/.	<u> </u>			
5a. Are there changes/concerns regarding human subjects research?] yes [] no	[] n/a
If there are changes or concerns, please note details.		-	_	_
5b. Has the gender/minority information been provided, and is recruitment/retention	[] yes	L] no
appropriate and on schedule?				
(The data for gender and minority recruitment need to be entered in the NIH				
Population Tracking System)	r	1	г	1
5c. For clinical trials, is there an acceptable plan for data and safety monitoring?] yes	L] no
http://ohrp.osophs.dhhs.gov/index.htm				
6. Are there changes/concerns regarding animal care and use?	Г] yes [1 no	[] n/a
If yes, please note details.	L.] yes [] 110	[] II/ a
If yes, preuse note details.				
http://grants.nih.gov/grants/olaw/olaw.htm				
7. In the text of the progress report, is an invention mentioned that is not noted on the	ſ] yes	Г] no
face page of the progress report?	-		•	•
If yes, what actions have been taken? (i.e., discuss with PI and report invention				
using IEdison Report Lite: https://dali.cc.nih.gov/erl/) (This link requires a				
password. Check with GMO for access.)				
www.iedison.gov				
http://odoerdb2.od.nih.gov/gmac/nihgps 2001/part iia 7.htm# Toc50481188				
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http://odoerdb2.od.nih.gov/gmac/nihgps 2001/part iia 6.htm# Toc50481186				
<u>1</u>				
Please note: Invention reporting is not required under funding agreements for				
educational purposes, per 37 CFR 401.1(2)(b).				
8. Are there other issues that should be resolved prior to issuing an award?	[] yes	[] no

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If yes, provide details.	